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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,427	11/28/2000	Peter Palese	7682-053	7446
20583	7590	06/28/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			MCKELVEY, TERRY ALAN	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,427

Applicant(s)

PALESE ET AL

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004 and 06 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-55 is/are pending in the application.
- 4a) Of the above claim(s) 41-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-40 and 47-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/21/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 35-40 and 47-55 in the reply filed on 4/16/04 is acknowledged. The examiner agrees to the rejoinder of claims 47-52.

Claims 41-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/16/04.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the

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relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

In the instant case, the substitute specification sets forth the claim for priority in the first sentence. However, the claim for priority lacks the previous claim of priority to 09/396,539, filed 9/14/99, now U.S. Patent No. 6,887,699 that was previously added by preliminary amendment filed 11/28/00. Additionally, two intermediate applications in the chain of continuity from 09/396,539 to the priority present in the substitute specification filed 4/6/05 is missing. The first paragraph of the specification should be amended to recite the following in order for the applicant's priority information to be correct and complete (this was made by adding the missing priority information to that supplied in the substitute specification and correction of one error in that data (07/440,053 was filed November 21, 1989, not November 24, 1989)):

This application is a divisional of application Serial No. 09/396,539, filed September 14, 1999, now U.S. Patent No. 6,887,699, which is a continuation of application Serial No.

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09/106,377, filed June 29, 1998, now U.S. Patent No. 6,001,634, which is a divisional of application Serial No. 08/252,508, filed June 1, 1994, now U.S. Patent No. 5,854,037, which is a continuation-in-part of application Serial No. 08/190,698, filed February 1, 1994 (abandoned), which is a continuation of application Serial No. 07/925,061, filed August 4, 1992 (abandoned), which is a divisional of application Serial No. 07/527,237, filed May 22, 1990, now U.S. Patent No. 5,166,057, which is a continuation-in-part of application serial No. 07/440,053, filed November 21, 1989 (abandoned), which is a continuation-in-part of application Serial No. 07/399,728, filed August 28, 1989 (abandoned).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

1. The oath/declaration has not been signed (or the signed oath/declaration has been lost from the application).
2. The oath/declaration has the wrong information for 07/440,053, the filing date is incorrectly indicated as November 24, 1989. The correct date is November 21, 1989.

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Specification

The substitute specification filed 4/6/05 has been entered.

Claim Objections

Claims 35-40, 47, and 51-55 are objected to because of the following informalities: "a RNA" or "a mRNA" are set forth which use the wrong indefinite article. The proper one is "an", so "an RNA" or "an mRNA" should be recited instead. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-52 are rejected under 35 U.S.C. 112; second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 47-52 are all drawn to a method of constructing a DNA molecule ... (describing the structure of the DNA molecule). However, only a preamble is recited without any method steps and thus it is unclear what steps are encompassed to result in the

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construction of a DNA molecule as claimed. Amending the claims to put in actual method steps would be remedial.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 47-52 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to methods that lack any method steps and thus are not actual methods. Because these claims are not actual methods or any other statutory subject matter, the instant claims are directed to non-statutory subject matter.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claim 35 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 27 of prior U.S. Patent No. 5,166,057 (Applicant reference 130). This is a double patenting rejection.

Claim 27 of '057 is drawn to a recombinant DNA molecule that is identical in scope to instant claim 35. The only difference between the two claims is that the recombinant RNA recited in claim 1 from which claim 27 depends recites "operatively linked to a heterologous RNA sequence comprising the reverse complement of an mRNA coding sequence" and instant claim 35 recites "operatively linked to an RNA sequence comprising the reverse complement of a mRNA coding sequence of a negative strand RNA virus". Because the claim 35 RNA sequence would appear to have to be heterologous by definition, then the scope would be the same. If the claim 35 RNA sequence does not by definition have to be heterologous, then a non-statutory double patenting would apply as set forth below for claim 35, in addition to the other claims rejected below.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010

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(Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-40 and 53-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8, and 27-29 of U.S. Patent No. 5,166,057 (Applicant reference 130). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims

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35-40 and 53-55 are either generic to all that is recited in claims 1-3, 8, and 27-29 of U.S. Patent No. 5,166,057 or would have been obvious based upon the limitations taught in the other claims of '057. That is, claims 1-3, 8, and 27-29 of U.S. Patent No. 5,166,057 either falls entirely within the scope of claims 35-40 and 53-55 or, in other words, claims 35-40 and 53-55 are anticipated by claims 1-3, 8, and 27-29 of U.S. Patent No. 5,166,057, or are obvious because the further limitations of instant claims 38-40 and 53-55 are drawn to influenza, influenza genome segment, or RNA template is replicable, all of which limitations that are either present or naturally present in the other claims of '057 (and thus it would have been obvious to modify claims 27-29 and the claims they depend on to result in the claimed DNA molecules of the same scope.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does

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submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and

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history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

June 26, 2005